Docket No. DEP-0639

VERTEBRAL ENDPLATE CHISEL

BACKGROUND OF THE INVENTION

The basic goal of a typical Posterior Lumbar Interbody Fusion ("PLIF") procedure is to remove a problematic disc, and insert a prosthetic fusion device (such as a cage or a mesh) into the empty disk space created by removal of the natural disc. However, the pathophysiology of an intervertebral disc is such that the disc space in which the disc sits is typically collapsed (e.g., 30-50% of the time) prior to disc removal. Once the natural disc is removed (but prior to implant insertion), the annulus and soft tissue surrounding the disk space tend to force the adjacent vertebrae to come even closer together, thereby increasing the extent of disk space collapse. Since one goal of the surgery is to restore the patient's anatomic disc space to the extent possible, there is a need to spread apart these collapsed vertebrae. In one conventional PLIF procedure, a flat Spreader (which resembles a butter knife) is inserted with a horizontal disposition into the collapsed disk space and then rotated 90 degrees to vertically distract the adjacent vertebrae and restore the patient's physiologic disc space. The distracted endplates are essentially parallel to each other after the Spreader is rotated.

In addition, it is further desirable that the implanted device be secure within the disk space. However, since the geometry of the disk space varies from patient to patient, and the implants are typically manufactured in only a few shapes, the implants do not typically fit congruently into the distracted disk space. Accordingly, in one conventional PLIF procedure, congruence between rectangular implant shapes and the distracted disc space height is achieved by forming rectangular channels of known dimension in the adjacent endplates.

However, the current PLIF procedure for forming substantially rectangular channels in the endplates is a time-consuming three-step process. After the full discectomy and careful distraction of the disk space by the Spreaders described above, the surgeon must first insert a Reamer into the disk space and rotate it to create rounded grooves in both the superior and inferior endplates. In a second step, the surgeon then must insert the leading edge of a Pilot Broach into the disc space and axially impacts it to create a rectangular channel on the posterior side of the endplates. In the third step, the

surgeon inserts a Finish Broach into the disc space and axially impact it to complete the anterior portion of the rectangular channel. Further details of the three-step Reamer - Pilot Broach - Finish Broach procedure and conventional instrument shapes can be found in a Brantigan et al. "Posterior Lumbar Interbody Fusion Techniques Using the Variable Screw Placement Spinal Fixation System" 6(1) in Spine: State of the Art Reviews. January 1992, pp. 175-200.

The Pilot Broach noted above has a body portion, a rectangular shaver portion extending distally from the body portion, and a cylindrical spreader portion extending from the shaver. The larger axial silhouette of the shaver portion relative to the cylindrical spreader portion defines shaving corners. The leading edge of the cylindrical spreader portion has a flat. Cylindrical spreader portion also includes an upper surface and a lower surface each of which bear upon the endplates. A crown is situated at the proximal end of the Pilot Broach and is used to engage a complimentary engagement connection.

Although the PLIF procedure using the Pilot Broach has been popular with surgeons, there have also been requests for improved instrumentation. In particular, surgeons have requested a quicker, easier 1-step method of preparing the rectangular channel in the endplates prior to implantation.

Figures 11b and 11c of US Patent No. 6,096,038 ("Michelson") discloses a combined distractor-cutter having a distracting portion (102 in Fig. 11b and 260 in Fig. 11c) and a rotary shaving portion (270 in Fig. 11b and 250 in Fig. 11c). The distracting portion distracts the vertebral bodies while the rotary cutting portion prepares a bore shaped for the insertion of the threaded circular fusion cage.

Since each of these devices uses a rotary cutting device to prepare the endplates, the channels formed thereby are not substantially rectangular. In addition, cannulated technology (which protects the internal organs from the rotary cutting devices) is often needed when drilling devices are used, thereby increasing the complexity of the procedure.

Figures 25 and 25a-d of US Patent No. 6,174,311 ("Branch") disclose a chisel having i) distracting portions 272, 273 for centering the chisel between the vertebrae and ii) upper and lower shavers 268, 270 for forming a rectangular channel in the distracted

vertebrae. Arms 267 and 269 define a cavity 276 for receipt of bone chips and shaving debris. Figures 37a-c and 38 of Branch disclose a second chisel substantially similar to the chisel of Figure 25.

One weakness of the Branch chisel lies in the disposition of both arms 267,269 and non-cutting edges 272, 273 at the lateral edges of the device. Because these arms and edges are disposed laterally, their effective widths essentially equal the entire width of the cutting edges, and thereby interrupt the surgeon's sightlines into the disk space.

US Patent No. 5,722,977 ("Wilhelmy") discloses a combination osteotome and spacer guide. In use, as in Figure 18, the spacer guide 8 is first inserted into the disc space 9. Next, the hollow osteotome 9 is slid over the outer dimension of the spacer guide 8 to its appropriate position. Lastly, driving head 49 of the osteotome is impacted by a mallet to drive the osteotome over the guide and into the vertebral bodies, and to cut and remove the desired amounts of bone.

One weakness of the Wilhelmy design lies in its need to slide the osteotome over the spacer guide in order to form the rectangular channel. Such sliding requires the maintence of close tolerances between the outer surface of the guide and the inner surface of the osetotome. This close tolerance may degrade with continued use. In addition, Wilhelmy teaches using separate osteotome and spacer guide instruments, thereby increasing complexity and cost. Another weakness of the Wilhelmy design lies in the relatively large width of the spacer. Since the width of the spacer must essentially equal the width of the osteotome to provide accurate cutting, the width of the spacer guide must be as large as possible. Accordingly, the surgeon's sightlines are interrupted by the device.

US Patent No. 4,697,586 ("Gazelle I") discloses a chisel having a spreader portion and a chisel configured to slide over the spreader . The surgeon using the Gazelle I device first inserts the spreader into the intervertebral space. Next, the chisel portion of the device is slid along the outer surface of the spreader and its shaving portions cut rectangular channels into the endplates.

A publicly used device ("Gazelle II") is somewhat similar to the Gazelle I device. Its main difference with Gazelle I is that the spreader of the Gazelle II device is rotatable. The surgeon using the Gazelle II device inserts the spreader into the intervertebral space

and then rotates it 90 degrees to distract the disc space. Next, the chisel portion of the device is slid along the outer surface of the rotated spreader and its shaving portions cut rectangular channels into the endplates.

Like Wilhelmy, the Gazelle I and II devices require sliding the shaving portions over the distractor portion. In addition, the box nature of the chisel obscures sightlines. Lastly, the spreader has a height to width ratio of about 3:2, and so is is not relatively thin.

US Patent No. 4,736,738 ("Lipovsek") discloses a shaving instrument for performing posterior lumbar interbody fusion, the instrument comprising a shaft adapted to be inserted into the intervertebral space and a chisel adapted to be slidably received within the shaft.

In sum, prior art procedures and devices used for endplate preparation suffer from:

a) the need to use multiple devices in multiple steps;

b) the need to slide a chisel over or through a spacer guide; and

c) the interruption of surgeon sightlines into the disc space.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having upper and lower portions, and proximal and distal portions,

b) an upper shaving portion extending distally from the upper base portion,

c) a lower shaving portion extending distally from the lower base portion,

the upper and lower shaving portions being disposed substantially parallel to each other and each having a width, and

d) a guide integrally connected to and extending distally from the base, the guide located between the shaving portions and having a width,

wherein the width of the guide is no more than 95% of the width of the upper shaving portion.

This device allows preparation of the rectangular channel in one step. After a full discectomy has been performed and careful distraction of the disc space has been achieved, the surgeon places the inventive device against the posterior lip of the endplate,

carefully aligns the instrument, and lightly impacts the device into the disc space to create the complete rectangular channel.

Since the width of the guide of the inventive device is less than the width of the upper shaving portion, the surgeon's sightlines into the disk space are not completely interrupted by the width of the guide as with the Branch device.

Since the shaving portions of the inventive device define substantially parallel planes (i.e., the shaving portion is not rotary), not only is a rectangular channel formed but also there is no need to use cannulated technology as with the Michelson device.

Lastly, since the guide of the inventive device is integrally connected to the base, shaving is performed by simply precisely locating the shaving portions at the desired depth of the vertebral surface and tapping the proximal end of the device with a hammer, and so does not require sliding the shaver over the guide as with the Gazelle and Wilhelmy devices.

DESCRIPTION OF THE FIGURES

Figure 1 discloses a first perspective view of a first embodiment of the inventive device.

Figure 2 discloses a perspective view of a distal portion of the first embodiment of the inventive device.

Figure 3 discloses a second perspective view of the first embodiment of the inventive device.

Figures 4a-4c disclose cross-sectional views through the base portion of three devices of the present invention.

Figure 5 discloses a side view of a second embodiment of the inventive device.

Figure 6 discloses another perspective view of a distal portion of the first embodiment of the inventive device.

Figure 7 discloses a side view of a distal portion of a third embodiment of the inventive device.

Figure 8 discloses a side view of a distal portion of the first embodiment of the inventive device.

Figure 9 discloses a perspective view of the first embodiment of the inventive device having been axially sliced.

Figure 10 discloses a perspective view of a fourth embodiment of the invention having cornered cutting tips..

Figure 11 discloses a side view of a fifth embodiment of the present invention.

Figure 12 discloses a side view of a sixth embodiment of the present invention.

Figure 13 discloses a perspective view of the sixth embodiment of the present invention.

Figure 14 discloses a perspective view of the fifth embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Now referring to Figure 1, the box chisel device 501 as a whole preferably has a proximal portion 503 and a distal portion 505. Preferably, the device includes distal base portion 507, an intermedite longitudinal portion 509 defining longitundinal axis A, and a handle portion 511 located proximal to the proximal portion of the base. The handle comprises a distal perimeter 521 and a proximal perimeter 523, the distal perimeter being smaller than the proximal perimeter .

Now referring to Figure 2, base portion 507 of the chisel may be shaped to have its own proximal portion 3 and distal portion 5. In some embodiments, as in Figure 3, the handle portion 511 at the proximal end of the device may terminate in a substantially flat surface 2 which provides an impact surface for a mallet or hammer. The proximal end may also be shaped without such a handle but with an extraction means so as to enable its connection to an extraction device. Preferably, the handle portion 511 comprises a female portion 4, as in Figure 3, or a male portion, for that purpose.

Now referring to cross-sectional Figure 4a, a cross-section of the base 507 includes upper portion 9,lower portion 11, and intermediate portion 13. In some embodiments, as in Figure 5, at least a portion of each of the upper 9, intermediate 11 and lower 13 portions of the base may have the same width W so that the shape of at least a portion 474 of the base may have a substantially blocky shape. In this embodiment, the proximal portion 474 of the base has a blocky shape.

Referring back to Figure 4a, in some embodiments, the base is shaped so as to provide pathways for the removal of bone debris from the area around the shaving portions. In some embodiments, the intermediate portion 13 has a width W_I which is thinner than the widths W_U and W_L of the adjacent upper 9 and lower 11 portions, thereby providing flutes 35 for removal of the debris.

Therefore, in some embodiments, as in Figure 4a, the base of the box chisel has an integral I-beam-like shape comprising :

i) an intermediate portion 13,

ii) an upper portion 9 integrally connected to the intermediate portion, and

iii) a lower portion 11 integrally connected to the intermediate portion,

wherein each of the intermediate, upper and lower portions has a width, and wherein the width of each of the upper and lower portions is greater than the width of the intermediate portion.

The I-beam-like shape includes the conventional I-beam shape, as shown in Figure 4a, a bulging I-beam shape, as in Figure 4b, and a bow-tie shape, as in Figure 4c.

The I-beam-like shape is advantageous because it minimizes the amount of material needed in the base section of the device, thereby maximizing debris pathway cross-section but without compromising the strength of the base section.

In some embodiments, upper 9 and lower 11 base portions do not contact the inner portion 470 of the intermediate portion, as in Figure 5, so that pathways for debris are formed between the inner surfaces of the upper and lower portions and the outer surface of the inner portion 470. In such embodiments, the upper and lower base portions may be integrally connected by virtue of lateral intermediate portions 472, Holes 476 may be provided in lateral portions 472 in order to assist debris removal.

Now referring to Figure 6, in some embodiments, in the proximal end of the I-beam-like portion of the base, the width of the intermediate section 55 widens towards the proximal end. This tapering directs the bone debris out of the pathway and prevents clogging.

In other embodiments, as in Figure 7, the intermediate portion 13 of the base extends from both the upper 9 and lower 11 base portions, and transitions into a neck 25 of guide 24.

Now referring to Figure 8, the upper and lower shaving portions should be oriented substantially parallel to one another in order to create a substantially rectangular channel between the vertebral endplates. Preferably, upper shaving portion 14 comprises an outer surface 61 and an inner surface 63 whose intersection forms a tip 15 having an angle α suitable for shaving endplates. Preferably, angle α is between 20 and 40 degrees.

When the angle α is more than 40 degrees, the device does not produce a clean cut. When the angle α is less than 20 degrees, the tip dulls quickly. Preferably, lower shaving portion 16 comprises an outer surface 65 and an inner surface 67 whose intersection forms a tip having the same angle α as that of the upper shaving portion. When the outer surfaces 61,65 of the shaving portions are parallel, the shaved bone is directed towards the debris pathways and a rectangular channel is formed.

Still referring to Figure 8, preferably, the head portion 27 of the guide extends further distally than the shaving portions. In this condition, the head 27 acts as a centering device which insures that the equal depth of bone is shaved from each adjacent endplate. More preferably, head 27 possesses upper and lower lands 20 which help stabilize the device as it moves through the disc space and assists in the centering function. Preferably, at least a portion of each the lands is positioned distal to the tips, 15, 17 of the shaving portions 14,16. These leading portions further stabilize the device upon its initial entry into the disc space, and prevent clogging.

Now referring to Figures 8 and 9, in some embodiments, the width of the distal end of the intermediate section narrows as it extends to form a pair of secondary orthogonal shavers 70,72. These orthogonal shavers are located between the upper and lower shaving portions 14,16 and are oriented orthogonal to the shaving portions 14,16. In one embodiment, the secondary orthogonal shavers 70,72 are located on either side of neck 25 from which the head 27 distally extends. Upon axial advance of the device, these secondary orthogonal shavers 70,72 further split the portion of the bone already shaved from the upper and lower shavers 14,16, thus preventing the bone from wedging into the device and being driven anteriorly.

Now referring to Figure 10, the general function of the guide 24 is to insure that the device is centered within the disc space so that equal amounts of bone are removed from each endplate. When the guide is centered between the shaving portions (i.e., its midpoint M is located between the 40% and 60% of the distance from edges Y and Z), substantially equal amounts of bone are removed from each endplate.

Preferably, the guide is shaped so as to minimize interruption of the surgeon's sightlines. In some embodiments, the guide has a thin width. When the guide has such a thin width, the surgeon can more easily see the disc space. Preferably, the guide width

WG is no more than 50% of the shaving portion width W_{SP}, more preferably no more than 25%. In some embodiments, the guide is centered between the widths of the shaving portions. When the guide is so centered, the surgeon can see the disk space as easily from one side of the device as the other.

In some embodiments, the guide is sufficiently thin and centered so that the entire guide width is located within the middle one-third of the width $W_{SP}$of the shaving portions. More preferably, the guide is sufficiently thin and centered so that the entire guide width is located within the middle one-fifth of the width of the shaving portions.

Now referring to Figure 2, in some embodiments, the guide 24 includes a neck portion 25 extending from the intermediate portion of the base and a head portion 27 extending from the neck. In some embodiments, as in Figure 2, the neck is rectangularly shaped. In other embodiments, as in Figure 11 the neck widens at an angle β as it extends from the intermediate extending portion to the head. In that embodiment, the angle β of the neck widening is substantially equal to the angle α formed by the tip of the shaving portion. In such embodiments, the bone debris pathway formed by the inner surface (e.g., inner surface 63) of the shaving portion and the relevant neck surface (e.g., surface 26) has parallel walls.

Still referring to Figure 11, in some embodiments, the distal section of the guide head 27 has a tapered portion 21. The tapered portion helps ease device into the distracted disc space. Preferably, the angle γ of the taper is between 30 and 60 degrees. When the angle is less than 30 degrees, the tapered portion must be very long. When the angle is more than 60 degrees, the taper is too blunt to achieve easy insertion.

In some embodiments, as in Figure 11, the axial cross section of the head has a nipple shape. That is, the cross section consists essentially of a tapered front section having little or no land portion. In other embodiments, and now referring to Figure 12, the axial cross section of the head has a bullet shape. That is, the cross section includes broad lands 320 and a tapered distal section 321.

Now referring to Figure 13, in some embodiments, the radial cross-section of the head has a circular shape. Preferably, however, the radial cross section of the head has a rectangular shape having a height and a width, as in Figure 6. Preferably, the rectangular or triangular shape is dimensioned so that the height H_H is at least 5 times the width W_H.

Although in preferred embodiments, the device is a single integral piece, in some embodiments, the device may be modular. For example, in some embodiments having a thin, centered guide, the shaving portions may be slidable over the outer surfaces of the guide.

Preferably, the device is made from either a metal or a ceramic material, or a composite of metals and ceramics. The device should be sterilized before use in a procedure. More preferably, the device is made of stainless steel.

Also in accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having upper, lower and intermediate portions, and proximal and distal portions,

b) no more than two shaving portions for contouring vertebral endplates, comprising:

i) an upper shaving portion extending distally from the upper portion, and

ii) a lower shaving portion extending distally from the lower portion,

the upper and lower shaving portions being disposed substantially parallel to each other to define a separation distance, each shaving portion having a vertically extending portion extending toward the opposite shaving portion for a distance of between 0% and 30% of the separation distance, and

c) a guide extending from the intermediate portion of the base.

Preferably, each vertically extending portion extends toward the opposite shaving portion for a distance of between 0% and 15% of the separation distance. More preferably, each shaving portion has substantially no vertically extending portion.

Also in accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having upper and lower portions, and proximal and distal portions,

b) an upper shaving portion extending distally from the upper portion,

c) a lower shaving portion extending distally from the lower portion,

the upper and lower shaving portions being disposed substantially parallel to each other, and

d) a single guide disposed between the shaving portions and extending distal to the shaving portions, and having a height and a width, wherein the height of the single guide at least 5 times greater than its width.

Also in accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having upper and lower portions extending distally therefrom,

b) an upper shaving portion extending distally from the upper portion,

c) a lower shaving portion extending distally from the lower portion,

the upper and lower shaving portions being disposed substantially parallel to each other, and

d) a single guide disposed between the shaving portions and extending distal to the shaving portions, and having a height and a width, wherein the width of the single guide no more than 50% of the width of the upper and lower shaving portion.

Also in accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having upper, intermediate and lower portions, and proximal and distal portions,

b) an upper shaving portion extending distally from the upper portion,

c) a lower shaving portion extending distally from the lower portion,

the upper and lower shaving portions being disposed substantially parallel to each other,

wherein the intermediate base portion narrows at the distal end thereof to form secondary orthogonal shavers.

Also in accordance with the present invention, there is provided a vertebral endplate chisel comprising:

a) a base having an integral I-beam-like shape comprising :

i) an intermediate portion,

ii) an upper portion integrally connected to the intermediate portion, and

iii) a lower portion integrally connected to the intermediate portion,

wherein each of the intermediate, upper and lower portions has a width, and

wherein the width of each of the upper and lower portions is greater than the width of the intermediate extending portion.

EXAMPLE I

Now referring to Figure 1, the Box Chisel 1 has a proximal portion 503 and a distal portion 505 formed along its longitudinal axis A. Now referring to Figure 2, at distal portion 505 is a rectangular base 507, having upper 9, lower 11 and intermediate 13 portions. Upper and lower portions 9 and 11 terminate in distally-extending upper and lower shavers 14,16. Intermediate portion 13 terminates distally in a flat thin guide 24 having a neck portion 25 extending from the intermediate portion 13 and a head portion 27 extending from the neck 25. Head portion 27 includes upper and lower land portions 20, upper and lower tapered portions 21, and a flat leading edge 23 formed by the termination of the tapered portions prior to their convergence. Tips 15, 17 of shavers 14,16 terminate distally before the head portion 27 forms its lands 20.

The overall shape of guide 24 can be described as a pancake-like. Now referring to Figure 6, in one exemplary sized 9 x 11 Box Chisel, the height H_H of the head (which corresponds to the disk height) is about 9 mm; width W_H of the head is about 2.5 mm, and the length L_H of the head is about 5 mm. Flat leading edge 23 of the head portion 27 typically has a height H_{LE} of about 5 mm. Finally, lands 20 typically have a length L_L of about 1 mm.

In addition, the device of Figure 6 contains a longitudinal groove 504 located along the upper surface of upper portion 9 of base 507. This groove reduces the stiction of the device during use.

In one method of using this device, once the disc space has been distracted by the Spreaders, the surgeon grips the Box Chisel by its proximal end and axially advances the distal end of the Box Chisel towards the distracted disc space. Since the disk space has already been distracted, tapered portions are the first portions of the tip to contact the vertebral endplates upon insertion into the disk space. If the disk space has been properly distracted, the flat leading edge portion of the tip should not contact the endplates. This initial contact between the tip tapers and the distracted endplates simply centers the Chisel Box relative to the adjacent vertebrae. Upon further axial advancement of the Box Chisel, tip contact with the endplates switches from the tapers to lands, and

then finally to both lands and shavers. In this last mode, the shavers cut the endplates to form the desired channels of known dimension, such shaving being guided by the land-endplate contact.

EXAMPLE II

In this embodiment, now referring to Figure 14, the base 207 of the box chisel 201 has an I-Beam-like section 208. The shavers 214,216 extend from the upper and lower base portions 209,211 and are formed by a height-increasing step 229 from the upper and lower base portions 209,211. The step reduces the stiction of the device. The guide 224 includes a i) neck portion 225 which widens as it extends distally and ii) a thin head portion 227 which has a rounded cross-section terminating in a flat leading edge 223.

EXAMPLE III

Now referring to Figure 12, this device includes a head 307 having lands 320 and a bullet-shaped distal section 321. The neck portion 325 of the guide includes both a rod-like section 360 and a widening section 361. The base 307 includes a substantially blocky proximal section 306 and an I-beam-like section 308.

EXAMPLE IV

Now referring to Figure 5, in this embodiment, the intermediate portion of the base comprises 413 has an inner portion 470, and lateral portions (one of which, 472 is shown). Inner portion 470 extends continuously from the proximal portion 474 of the base, while the lateral portions form the sides of a hollow box around inner portion 470. In some embodiments, the lateral portions include side holes 476. Guide 424 extends from the inner portion 470 of the intermediate base portion 413 and has a bullet shaped, radially symmetric cross section.